

REMARKS

The Office Action dated March 24, 2009 has been carefully reviewed. Applicants would like to thank the Examiner the considerate approach taken to this filing. In the instant case claims 2, 6-7, 11-16, 18 and 20 are pending. Claims 1, 3-5, 8-10, 12, 17, 19 and 21-22 have been cancelled. Claims 2, 6, 11, 14, 18 and 20 have been amended. No claims have been added.

Reconsideration of the previous claim rejections is respectfully requested.

Applicants believe that the amendments made herein along with the remarks provided serve to put all the remaining claims in condition for allowance. Given the above, it is specifically and respectfully requested that the Examiner enter and allow the claims as amended herein.

The Information Disclosure Statement

Applicants note the Examiner's recitation of the IDS as in improper format. Respectfully, this will be resolved with a contemporaneously filed IDS in proper format with the appropriate references in a separate paper in compliance with § 609.04(a).

Co-Pending Applications

Applicants note the Examiner's concern for other patent applications that may affect or are material to the patentability of the current application in compliance with the MPEP. Respectfully, Applicants have no knowledge of such applications at this time. Should Applicant become aware of such existing applications or prior art Applicants will bring it before the Examiner. MPEP 2001.06(b).

In the Specification

Applicants have reviewed Examiner's comments with regard to the instant specification and will bring changes/amendments forward for the Specification as those are identified in cooperation with the Examiner.

The Rejection Under 35 U.S.C. §112, first paragraph

The Examiner has rejected claims 1-22 under 35 U.S.C § 112, first paragraph as a written description sufficient to enable one skilled in the art to make or use the invention. Respectfully, given the amendments made this rejection is traversed and reconsideration is requested.

As regards any lack of enablement, the specification is sufficient for those in the relevant scientific fields to quickly understand the significance of, and how to isolate both the individual compounds named and the widely available commercial compounds identified as oxazalone. The issue of adequate enablement depends on whether one skilled in the art could reproduce the claimed invention without "undue experimentation." The standard in this inquiry was supplied by the Federal Circuit when that court announced that enablement by a disclosure is not precluded even if some experimentation is required, the only limiting factor is that this experimentation must not be "undue." *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). In *Wands* Judge Smith decided that the key word in this formula is "undue" not "experimentation" and applied a reasonableness standard, given the nature of the invention and the state of the art when he stated:

"The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is **merely routine**, or if the specification in question provides **a reasonable amount of guidance with respect to the direction in which the experimentation should proceed.**" *Wands* at 737 (emphasis added).

The point of the above quote is that when the Applicants, as in the instant specification, provide a series of working examples, give extensive guidance to appropriate protocols through the specification – including references to **old, well-known, and well understood laboratory protocols**, referenced many citations in the literature, any experimentation that may be necessary, becomes routine. Respectfully, this is also true with regard to obtaining/purchasing well known chemical compounds. By citing the appropriate protocols, identifying needed chemical intermediaries and showing the interaction and how the chemical intermediaries or starting agents interact to reach a desired end result the practitioner in the field no longer need worry that a certain molecule, like those specified in the instant specification, can be developed and isolated, it is known to a certainty that it will. The working example built by the Applicants provides this assurance, and makes irrelevant the difficulties that an inexperienced practitioner may have in referencing the appropriate protocol.

More to the point, many of the characteristics of how to “build” the compounds specified in the Specification are well known in the field and may be employed in the effort to isolate these molecules from others found in a reaction sample. The size, weight, relative charge, and sequence of the molecules are known in the art. The method of Applicants and the purpose of the application announces the importance of measuring the levels and/or other changes in these molecules. All of these factors provide a worker in the field with more than enough information to isolate and purify the molecules of interest.

The protocols disclosed in the specification, provide the public the ability to practice the invention, essentially by providing a detailed map leading towards a goal that has already been reached, regardless of the state of the art prior to the application. In conjunction with the extremely high level of skill in the field, it is clear that the specification, as tempered by the relevant case law discussed above, does enable other workers in the field to make and use the invention without “excessive” experimentation. *Wands* at 740. This level of disclosure is **more than** what is necessary for a specification to provide. In determining whether the disclosure requirement is satisfied, the person(s) *skilled* in the art are *presumed* to be aware of all of the relevant literature, including trade publications, textbooks, technical journals, U.S. patents, and *old well-known laboratory protocols*. The answer provided by the Federal Circuit on this point is

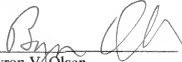
that enablement is not precluded even if some experimentation is required.” *In re O’Farrell*, 853 F.2d 894, 7 USPQ2 1673 (Fed. Cir. 1988); MPEP § 2164.01; and *In re Wands*, 858 F.2d 731.

Therefore, the Examiners rejection of the claims under 35 U.S.C. § 112, first paragraph, is traversed, and reconsideration of the claims is, respectfully, requested.

Response to Remarks and Amendment

The Examiner’s response to Applicants election is noted. For the purposes of further clarification Applicant has made an effort to amend the claims in line with the Examiner’s suggestions relative to the selection of a species to pursue further prosecution. This will reduce the burden on the Examiner with regards to researching multiple groups and move towards claims enabled by the invention Reconsideration is respectfully requested.

Respectfully submitted,


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